UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

ETHEL KELLOGG, Plaintiff, v. WYETH, Individually and as Successor-in-Interest to A.H. ROBINS COMPANY, INC. and AMERICAN HOME PRODUCTS CORPORATION; SCHWARZ PHARMA, INC.; ACTAVIS, INC.; ACTAVIS-ELIZABETH, L.L.C.; ALPHARMA, INC.; PUREPAC PHARMACEUTICAL COMPANY, INC.; TEVA PHARMACEUTICALS, USA, INC.; BAR PHARMACEUTICALS, INC.; PLIVA, INC.; and DRUG COMPANY DOES 1 THROUGH 10, inclusive, Defendants.	:	Case No. 2:07-cv-82

MEMORANDUM OPINION AND ORDER

Plaintiff Ethel Kellogg has brought suit against the brand name and generic manufacturers of metoclopramide for injuries arising from her ingestion of the drug. She alleges that the medication caused her to develop tardive dyskinesia, a neurological disorder causing involuntary repetitive tic-like movements. Following the United States Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), Defendants Actavis Elizabeth LLC, Barr Pharmaceuticals, LLC and PLIVA, Inc. (collectively "Generic Defendants") have moved for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), contending that all claims against them are preempted. For the reasons that follow, the motion, ECF No. 288, is **granted**.

Kellogg's request for permission to move to amend her Second Amended Complaint ("SAC") is **denied**.

I. Background

The Food and Drug Administration ("FDA") approved metoclopramide in tablet form for the treatment of gastrointestinal disorders under the brand name Reglan in 1980.[1] Generic manufacturers received approval to produce metoclopramide in 1985. According to Kellogg's SAC, the Generic Defendants knew or should have known that the labeling for metoclopramide substantially understated the risk of developing tardive dyskinesia, particularly as a result of long-term use of the drug.

Warnings included in labeling for metoclopramide have been modified and strengthened over the years, in 1985, in 2004, and in 2009. *Mensing*, 131 S. Ct. at 2572-73. In 2004, the FDA approved a change to the label to add that "[t]herapy should not exceed 12 weeks in duration." *Id.* at 2573; *see also Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 427 (D. Vt. 2008). In 2009, the FDA required the addition of a "black box warning," stating that "Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. . . . Treatment with metoclopramide for longer than 12 weeks should be

[1] The FDA regulates the manufacture, sale, and labeling of prescription drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended. 21 U.S.C. §§ 301-399d.

avoided in all but rare cases." *Mensing*, 131 S. Ct. at 2573.

Ethel Kellogg was prescribed and took metoclopramide from May 2000 to May 2004 for gastroesophageal reflux disease. Her SAC alleges claims against the Generic Defendants for negligence (Count Four), negligence per se (Count Five), strict products liability (Count Six), and breach of express and implied warranties (Counts Seven and Eight). In her General Allegations of Fact, she asserts that her injuries "came about as a foreseeable and proximate result of the drug company defendants' dissemination to physicians of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential effects of exposure to metoclopramide and the ingestion of metoclopramide products. SAC ¶ 31, ECF No. 85. Further, she alleges that the Generic Defendants

> knew or should have known about the false and misleading information and the omitted information in the package inserts for metoclopramide and the PDR monograph for Reglan, knew or should have known about the widespread tendency among physicians to prescribe metoclopramide for long-term use and knew about the substantially increased prevalence of tardive dyskinesia and other serious extrapyramidal side effects of metoclopramide, particularly when it is prescribed for long-term use and, notwithstanding this knowledge, consciously decided to ignore this information, rather than urgently propose new labeling to the FDA or send "Dear Healthcare Practitioner" letters to physicians, in order to warn physicians about the danger associated with long-term use of metoclopramide.

Id. ¶ 36. In their essence, Kellogg's claims are "traditional products liability claims for injuries caused by [the Generic

Defendants'] . . . failure to provide adequate warnings for their products," that allege specifically that her "doctors prescribed the drug for prolonged use because they were not adequately informed about the risks of prolonged exposure to the drug." Pl.'s Resp. 1-2, 9, ECF No. 289.

Specifically, Kellogg asserts that the Generic Defendants were negligent in "failing to exercise reasonable care in [their] labeling of [metoclopramide] products for their effects in ordinary and foreseeable uses, including long term use, and in [their] dissemination to physicians of information concerning the products' effects. . . ." SAC ¶ 58. As negligence per se, Kellogg asserts that the package inserts and other labeling for metoclopramide failed to conform to statutory requirements. *Id.* ¶¶ 63-64. In her strict product liability claim, Kellogg asserts that metoclopramide was defective and unreasonably dangerous because it was not distributed with adequate warnings and instructions for use. *Id.* ¶ 67. Kellogg asserts that the Generic Defendants breached an express warranty because generic metoclopramide materially failed to conform to their representations concerning its properties and effects, made in package inserts and otherwise. *Id.* ¶ 70. She asserts that the Generic Defendants breached implied warranties that their products were of merchantable quality and "fit for their common, ordinary and intended use in long term therapy for the treatment

of chronic and/or intermittent gastroesophageal reflux and/or gastroporesis." *Id.* ¶ 75.

On January 13, 2011, this Court granted a partial stay of proceedings in anticipation of a decision by the United States Supreme Court in the consolidated cases of *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), and *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). The Supreme Court issued its decision on June 23, 2011. *See Mensing*, 131 S. Ct. at 2567.

In *PLIVA, Inc. v. Mensing*, the United States Supreme Court held that federal law preempted state laws imposing a duty on generic drug manufacturers to provide adequate warning labels for their products. *Id.* at 2572, 2581. Like Ethel Kellogg, the plaintiffs in the consolidated cases before the Court were prescribed and took generic metoclopramide. After taking the drug for several years, these women developed tardive dyskinesia. *Id.* at 2573. Their lawsuits alleged "that long-term metoclopramide use caused [their] tardive dyskinesia and that the [generic manufacturers] were liable under state tort law . . . for failing to provide adequate warning labels." *Id.*

The *Mensing* Court first identified a state tort duty to warn, that allegedly would require the generic manufacturers to use a stronger, safer label than the one approved by the FDA. The Court then summarized the different labeling requirements for

brand-name and generic drug manufacturers, observing that under the Drug Price Competition and Patent Term Restoration Act of 1984,[2] a generic drug manufacturer "is responsible for ensuring that its warning label is the same as the brand name's." *Id.* at 2574.

The Supreme Court rejected the suggestions that generic drug manufacturers have opportunities to strengthen their warnings, either (1) through the FDA's "changes-being-effected" process, or (2) through the delivery of "Dear Doctor" letters to healthcare professionals. *Id.* at 2575-76. It assumed, without deciding, that generic drug manufacturers have a duty to propose that the FDA require stronger warning labels, but concluded that complying with such a duty would not satisfy a state-law duty to provide adequate labeling. *Id.* at 2576-78. Consequently, the Court concluded that it is impossible for generic manufacturers to comply both with state requirements to supply an adequate warning label and federal requirements that their labels be the same as the brand name's label. *Id.* at 2577-78. Given that the Supremacy Clause establishes that federal law prevails in cases of direct conflict with a state law, the Court held that the plaintiffs' failure to warn claims against the generic manufacturers were preempted. *Id.* at 2577, 2581.

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[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the "Hatch-Waxman Amendments."

In their motion, the Generic Defendants argue that the decision in *PLIVA* disposes of all of Kellogg's claims against them. Kellogg, however, contends that her claims are preempted only to the extent that they are based on failure to provide adequate warnings through the labeling for metoclopramide. She argues that federal law permits generic prescription drug manufacturers to disseminate truthful, nonmisleading information to doctors about the risks associated with their product through means other than labeling, and that therefore it was not "impossible" for the Generic Defendants to comply with both state and federal requirements.

II. Discussion

A. Rule 12(c) Motion

"'To survive a Rule 12(c) motion, [plaintiffs'] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Hayden v. Paterson*, 594 F.3d 150, 160 (2d Cir. 2010) (quoting *Johnson v. Rowley*, 569 F.3d 40, 44 (2d Cir. 2009) (per curiam)). The Court accepts as true all well-pleaded factual allegations, and draws all reasonable inferences in plaintiff's favor. *L-7 Designs, Inc. v. Old Navy, LLC*, 647 F.3d 419, 429 (2d Cir. 2011).

In considering a motion for judgment on the pleadings, a court may first identify pleadings that, being no more than conclusions, are not entitled to the presumption of truth. *Id.*

at 430; *see Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). Assuming the truth of well-pleaded factual allegations, a court may then determine whether they plausibly entitle the pleader to relief. *L-7 Designs*, 647 F.3d at 430; *see Iqbal*, 129 S. Ct. at 1950. The Court therefore examines the factual allegations of Kellogg's SAC, independent of their characterization as claims of negligence, product liability or breach of warranty.

B. The Allegations of Failure to Provide Adequate Labeling

"Label" is defined in the Food, Drug, and Cosmetic Act as "a display of written, printed, or graphic matter upon the immediate container of any article . . . ." 21 U.S.C. § 321(k). "Labeling" "means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). For purposes of regulating prescription drug advertising, the FDA interprets labeling broadly, to include

> [b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug. . . .

21 C.F.R. § 202.1(l)(2). Such labeling must be "consistent with and not contrary to . . . approved or permitted labeling." *Id.* §

201.100(d)(1); *see PLIVA*, 131 S. Ct. at 2576 (deferring to the FDA's interpretation, and concluding that federal law did not permit drug manufacturers to issue additional warnings through "Dear Doctor" letters).

Federal law permits drug manufacturers to provide information about off-label uses[3] of their drugs, as long as the information does not recommend or suggest the unapproved use, and is not inconsistent with or contrary to the approved labeling for the drug. *See* 21 C.F.R. §§ 201.100(d)(1) (requiring labeling to be consistent with and not contrary to approved or permitted labeling); 202.1(e)(4)(i)(a) (prohibiting advertisements that recommend or suggest any use that is not in the accepted labeling).

Kellogg concedes that her claims that the Generic Defendants failed to provide the medical community with adequate warnings about metoclopramide through labeling or advertising are preempted. She contends, however, that *Mensing*'s holding does not preclude a claim that the Generic Defendants are liable for failing to disseminate accurate, nonmisleading information about metoclopramide, including warning information about dangerous

[3] An "off-label" use is a use of the drug that has not been approved by the FDA. The FDA does not prohibit physicians from prescribing drugs for off-label uses, but does prohibit drug manufacturers from promoting off-label uses, through its misbranding and intended-use regulations. *See* 21 U.S.C. § 352(a)-(n); 21 C.F.R. § 201.128.

side effects, through means other than labeling or advertising.

C. The Allegations of Failure to Provide Adequate and Accurate Information Through Other Means

Although Kellogg makes the argument that it was possible for the Generic Defendants to provide accurate, nonmisleading information about metoclopramide, she acknowledges that such distribution can constitute a misbranding of the product if it includes information that is inconsistent with or contrary to FDA-approved labeling. Pl.'s Resp. 15; *see* 21 C.F.R. § 201.100(d)(1). She urges recognition of the possibility, however, that the Generic Defendants could have disseminated accurate information about the unapproved use of metoclopramide for long-term therapy without violating the FDCA, as long as the information did not constitute promotion of the unapproved use. Pl.'s Resp. 19-30. In support of this interpretation she offers statements from the Government's briefs in a pair of cases which allow that drug manufacturers do not necessarily violate the misbranding provisions of the FDCA by making statements about the safety or effectiveness of an unapproved use of a drug. *See* Supplemental Brief for the United States at 17, *United States v. Caronia*, No. 09-5006-cr (2d Cir. Aug. 30, 2011); Defendants' Memorandum of Points & Authorities in Support of Motion to Dismiss or for Summary Judgment at 34-35, *Allergan v. United States*, No. 09-1879(JDB) (D.D.C. Jan. 11, 2010). Indeed, the Government asserts that it has affirmatively encouraged drug

manufacturers to disseminate warnings about unapproved uses of their drugs, *Allergan* Br. at 36, warnings which obviously do not appear on any approved labeling.

However valid or reasonable this interpretation of "labeling" and the federal duty to avoid misbranding may be, *Mensing* now bars a lawsuit against a generic manufacturer for failing to provide additional information about the safety of metoclopramide, whether for an approved or an unapproved use. In *Mensing*, the Supreme Court concluded that "Dear Doctor" letters, which qualify as "labeling," could not transmit "substantial new warning information" because the letters "would not be consistent with the drug's approved labeling." *Mensing*, 131 S. Ct. at 2576. It is the "federal duty of 'sameness,'" *id.* at 2575, that trumps a state law duty to provide adequate warnings.

Kellogg offers no viable reason to distinguish between "Dear Doctor" letters and other forms of "labeling," such as reprints of journal articles or materials produced in connection with continuing medical education programs. *See* 21 C.F.R. § 202.1(l)(2) (defining labeling to include virtually any type of audio, visual or printed matter descriptive of a drug and supplied by a manufacturer). Regardless of whether the warning information is offered for promotional or educational purposes; regardless of whether the warning information is directed toward an approved or an unapproved use; *Mensing* declares that material

which satisfies the definition of labeling cannot be proffered by generic manufacturers without running afoul of the requirements that the information be consistent with and not contrary to the approved labeling, and that the information not imply a therapeutic difference between the brand and generic drugs. *Mensing*, 131 S. Ct. at 2576.

To the extent the Kellogg's SAC can be read to assert liability against the Generic Defendants for failure to provide adequate warnings through dissemination of nonpromotional information, these claims are also preempted.[4]

III. Conclusion and Order

Because state tort claims against generic drug manufacturers for failure to provide adequate warnings are preempted to the extent they would require the generic drug manufacturers to provide stronger or safer labeling than that approved for the brand name drug, Kellogg's claims against the generic

[4] Given that Kellogg's claims against the Generic Defendants must be dismissed on preemption grounds, the Court does not address their argument, made in their Reply brief, that Vermont law does not recognize a duty on the part of drug manufacturers to disseminate information regarding off-label use, or to disseminate information separate from their products. *See* Reply 8-9, ECF No. 294. The Court notes merely that Vermont recognizes a manufacturer's duty to warn, *see, e.g.*, *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044-45 (2d Cir. 1995) (applying Vermont law); *Webb v. Navistar Int'l Transp. Corp.*, 692 A. 2d 343, 347 (Vt. 1997). The scope of the duty to warn and the adequacy of the warnings are "properly left to the jury deliberating with the guidance of appropriate instructions." *McCullock*, 61 F.3d at 1045 (quotation marks and citation omitted).

manufacturers must be dismissed. Because amendment of her SAC would be futile, given that the theories she has asserted in her SAC and her Response are all preempted, her request for leave to amend on that basis is denied. The Generic Defendants' Motion for Judgment on the Pleadings, ECF No. 288, is **granted.**

On September 28, 2011, the Court stayed the filing of pretrial motions until resolution of any motion filed in connection with the *Mensing* decision. This motion having been resolved, the deadline for pretrial motions, including *Daubert* motions and dispositive motions, is March 1, 2012.

Dated at Burlington, Vermont this 3rd day of February, 2012.

/s/ William K. Sessions III
William K. Sessions III
United States District Judge